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APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,533	11/27/2001		Anders Larsson	HO-P02300US0	9584
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FULBRIG!	HT & JAV	WORSKI, LLP	HANLEY, SUSAN MARIE		
1301 MCKINNEY SUITE 5100				ART UNIT	PAPER NUMBER
HOUSTON		10-3095	1651		

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
•	09/937,533	LARSSON ET AL.				
Office Action Summary	Examiner	Art Unit				
	Susan Hanley	1651				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 27 November 2001.						
2a) This action is <b>FINAL</b> . 2b) ⊠ This						
,—	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
<ul> <li>4)  Claim(s) 1-8,10-13 and 15-31 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1-8,10-13 and 15-31 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>						
Application Papers						
9) The specification is objected to by the Examine	er.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)         Paper No(s)/Mail Date <u>9/24/01</u>.     </li> </ol>	4) Interview Summar Paper No(s)/Mail E 5) Notice of Informal 6) Other:					

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#### Claims Suggestion

For ease of reading, it is suggested that claim 1 be amended as follows:

1. A method for making a substrate surface permanently more hydrophilic compared to an untreated substrate surface, wherein said more hydrophilic substrate surface comprises a channel, having a depth of  $<1000\mu$ , to serve as a liquid transportation system and is made from a plastic material comprising:

treating an untreated substrate surface with a non-polymerizable gas plasma, wherein the intensity of the plasma is selected so that the treated substrate surface becomes permanently more hydrophilic compared to the untreated substrate surface.

### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "more hydrophilic" in claim 1 is a relative term which renders the claim indefinite. The term "more hydrophilic" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "comprising a surface in uncoated form" is unclear. Is the substrate surface uncoated before or after the plasma gas treatment in claim 1? Or does "coating" refer to the plasma gas treatment itself?

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-12, 17-21, 28 and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Chang et al. (1999).

Chang et al. teach that a polycarbonate surface, as in claims 28 and 29, surface was modified with ammonia gaseous plasma (p. 231, first paragraph),. The contact angle of the surface decreased from 77° to about 20-40° (p. 235, Table 2), as in claims 10-12 and 17-21. Chang et al. evaluated the ability of 3T3 fibroblasts to adhere to the modified surface. The fibroblasts were cultured in a medium that contained 10% fetal bovine serum (p. 233, third paragraph), as in claim 20. The adhesion strength of the fibroblasts increased significantly on the modified sheet, by at least about 50% (compare Figures 7 and 8), as in claims 19 and 21. Chang is silent regarding the limitation for the water contact angle of the modified surface after washing with an aqueous alcoholic solution. However, this is considered to be an inherent property of the modified polycarbonate surface. The contact angle of a surface is a property that results from the composition and structure of the surface. A polycarbonate surface that has been treated to give a structure with a certain contact angle would be expected to react to the washing limitations in the same manner as claimed. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing."; see In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Claims 10-12, 17-19 and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Dekker et al. (1991).

Dekker et al. disclose a method of modifying surfaces comprising polytetrafluoroethylene (Teflon) by nitrogen and oxygen gas plasma treatments to render the surface more hydrophilic and susceptible to cellular adhesion. Polytetrafluoroethylene film (PTFE) surfaces were subjected to gas plasma treatment at an electrode power of 250 to 300 W. Contact angles of the unmodified surfaces were 94-99°. The contact angle after treatment was between 15-57° (p. 132, bottom left column, page 133, Table 1), which was a change of 40-75% in contact

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angle. Endothelial cells were cultured in 20% serum-containing culture medium on the treated and untreated PTFE surfaces. Plasma-treated films having contact angles of 20-45° had more cellular adhesion than untreated or TCPS, tissue cultured polystyrene, the reference surface (p. 135). Dekker et al. are silent regarding the limitation for the water contact angle of the modified surface after washing in an aqueous ethanolic solution. The contact angle of a surface is a property that results from the composition and structure of the surface. A PTFE surface that has been treated to give a structure with a certain contact angle would be expected to react to the washing limitations in the same manner as claimed. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing."; see In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

Claims 10, 11, 17-19, 28, 29 and 30 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Komvopoulos et al. (US 6,685,743)

Komvopoulos et al. disclose a method for treating plastic surfaces with different types of plasma gases to render the surfaces more hydrophilic. Plasma gas treatment can be applied to a surface, wherein the power intensity is between 2 and 5 Watts per square cm, as in claim 2 (col. 5, lines 55-68). The flow rate of the gas is about 50 to 2000 sccm (col. 6, lines 20-30), as in claim 3. The polymers can comprise polyethylene, polymethacrylate and polyurethane, as in claims 5, 11, 25, 28 and 29 (col. 6, lines 42-68). Depending on the reaction conditions, one result of the treatment is the cross-linking of polymers in a localized manner (abstract), as in claim 30. The plasma gas can be generated by radio-frequency energy (col. 7, lines 1-2), as in claim 6. The power can range from about 200 to 400 Watts, based on the power densities Table 1 and the area of the treated disk, 45.6 square cm (col. 7, lines 24-55), as in claim 3. Komvopoulos et al. are silent regarding the limitation for the water contact angle of the modified surface after washing in an aqueous ethanolic solution. The contact angle of a surface is a property that results from the composition and structure of the surface. A polymeric surface that has been treated to give a structure with a certain contact angle would be expected to react to the washing limitations in the same manner as claimed. "From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing."; see In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

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Claims 10, 11, 27-29 and 31 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Anders et al. (6,022,553).

Anders et al. disclose a method for making antimicrobial blood-compatible surfaces suitable for medical uses The surfaces comprise polymeric substrates including hydrophilic homo- and co-polymers. The monomers include polyolefins, vinylaromatic monomers, polycarbonates and the like. The copolymers can be mixed (col. 2, lines 53-68), as in claims 11 and 27-29 and 30. The polymers should have a contact angle with water that is less than 30° because polymers or copolymers having a contact angle of more than 30° are not adequately hydrophilic (col. 3, lines 13-20), as in claim 10. The disclosed surfaces are made by treating said polymeric surface with plasma gas comprising SO<sub>2</sub> between 400 to 2000 Watts, as in claim 18. A noble gas can also be employed (col. 3, lines 38-60).

Claims 1, 5, 7, 8, 15 and 16 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sheppard et al. (US 6,143,247).

Sheppard et al disclose an affinity-based platform for detecting and quantifying particulate matter in a fluid. The particulate specie is a cell. The platform can be made from polyethylenes, or poly (vinylidene) fluoride, both of which come from the polymerization of unsaturated monomers, as in claims 5 and 16. The surface properties of the platform material can be modified to encourage or suppress cell binding. The surface modification can be achieved by chemical treatment with inert-gas plasma (col. 16, lines 1-15), as in claims 1 and 7. This disclosure meets the limitations of claim 7 because a noble gas is inherently inert. Treatment of the platform with inert-gas plasma and polymer that is hydroxyl-rich will cause the surface of the platform to become more hydrophilic (col. 17, lines 55-68). The surface of the platform can be further modified by attaching biomolecules that have specific binding affinity, such as antibodies, receptor/ligands, integrins, and the like (col. 10, lines 7-14 and 33-50), which meets the limitation regarding "bioaffinity" group as in claim 8.

The platform comprises microchambers and microchannels that connect the microchambers. The depth of the microchannel ranges from 0.1  $\mu$  to 1 mm thickness of the platform (col. 20, lines 1-10), as in claim 1. Sheppard discloses that fluorescence detection is the preferred method to detect cells. The platform comprises a material that is specifically transparent to light of a particular wavelength which permits spectral properties of the light to be

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determined by the dye used to illuminate a particulate (cell) retained in a chamber (col. 22, lines 47-61). Sheppard et al. teach a platform having a dye chamber that is filled with ethidium bromide (col. 34, lines 13-16), as in claim 15. This disclosure meets the limitation of claim 18 because Sheppard et al. teach a platform with channels of less than 1 mm in depth that is a platform that is transparent to light of a particular wavelength does not absorb energy from the light. Since the light does not absorb energy, the platform can not fluoresce and by definition has a fluorescent intensity of zero.

Although Sheppard et al. do not refer to the platform as a kit, the platform characteristics meet this limitation. According to Webster's 11 Dictionary, a kit may be defined as: 1. a set of articles used for a particular purpose, 2. a set of parts or materials to be assembled, 3. a packaged set of related materials, or 4. a container for a kit (p. 667). The modified platform taught by Sheppard et al. comprises a set of materials for the specific purpose of culturing cells.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6, 10, 13, 17, 22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. (US 6,143,247) in view of the combined disclosures of Komvopoulos et al. (US 6,685,743), Dekker et al. (1991) and Anders et al. (6,022,553).

The disclosure of Sheppard et al. is discussed vide supra.

Sheppard et al does not teach how the plasma gas is generated, the parameters for the gas plasma reaction, a plastic material having a water contact angle of <30°, wherein said angle is changed less than +20% after washing with water/ethanol solution or to employ substrates comprising a copolymer or a monomers with unsaturated characteristics.

The disclosure by Komvopoulos et al., Dekker et al. and Anders et al. are discussed vide supra.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to use RF power to generate the plasma gas, utilize the reaction parameters taught by Komvopoulos et al., Dekker et al. and Anders et al., make a plastic material having a water contact angle of <30°, wherein said angle is changed less than +20% after washing with water/ethanol solution and to employ a copolymer or a monomers with unsaturation for the substrate surface. The ordinary artisan would have been motivated to do so because the making of such choices were shown by Komvopoulos et al., Dekker et al. and Anders et al. to be well known in the art and within the purview of the ordinary artisan to select such variables.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a modified surface having a contact angle of  $>20^{\circ}$  and  $<30^{\circ}$  because cells in a culture adhere to surfaces that are more hydrophilic. This characteristic is desirable in order to increase the yield of cells in a culture. The ordinary artisan would have had a reasonable expectation that he or she could make surface having those properties because the prior art has demonstrated how to accomplish this by disclosing parameters and substrates for gas plasma reactions for this purpose.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

UEAN C. WITZ PRIMARY EXAMINER